K043350

DEC 15 2004

510(k) Summary

Submitter: Apollo Medical Imaging Technology Pty. Ltd
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Date Prepared: September 30, 2004

Contact Person: Qing Yang

Device Trade Name: MIStar

Device Common Name: Picture Archiving Communications System (PACS)

Regulation Number: 892.2050

Device Classification: Class II

Classification Name: Image Processing System

Predicate Device:

Manufacturer	Product	510(k) Number	Clearance Date
Efilm Medical, Inc.	Efilm Workstation with Modules	K020995	04/12/2002
General Electric	CT Perfusion 2	K010042	01/30/2001
GE Medical Systems	Advantage Windows with Functool Option	K960265	07/03/1996

Device Description

MIStar is a software package, which runs on an Intel-based PC platform. It allows manipulation, visualization and processing of medical images acquired with various clinical scanners and stored in DICOM and /or other proprietary formats. MIStar allows transfer of DICOM 3.0 images over a medical imaging network.

MIStar also provides post-processing of dynamic CT and MR images acquired during and after the injection of a compact bolus of contrast media, where the contrast media acts as a pure intravascular tracer. It allows visual inspection of time intensity curves and calculation of parametric parameters (i.e., area under curve, time to peak, maximum slope of enhancement, etc). It also allows calculation of various perfusion related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability) from dynamic CT data. The results are displayed in a user-friendly graphic format as parametric images that provide supplementary information for diagnosis purposes.

Indications for Use

MIStar is a software package that provides manipulation, visualization and processing of medical images in a diagnostic imaging setting. It allows transfer of DICOM 3.0 images over a medical imaging network, and can receive digital images and data from various sources (including but not limited to CT, MR, NM, and PT).

MIStar supports the analysis of dynamic CT and MR images acquired during and after the injection of a compact bolus of contrast media. It allows visual inspection of time intensity curves and calculation of parametric parameters (i.e., area under curve, time to peak, maximum slope of enhancement, etc). It also calculates various blood perfusion related parameters such as blood flow (BF), blood volume (BV), mean transit time (MTT) and capillary permeability from dynamic CT images. This software provides supplemental information to those images extracted from CT and MR temporal datasets and will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes related but not limited to stroke or tumor angiogenesis and be helpful in therapy monitoring.

MIStar is intended to be used by trained medical professionals, including but not limited to licensed radiologists, technologists and clinicians, and for the rendering clinical diagnosis.

Conformance to Standard

MIStar provides DICOM functionality in conformance to the ACR-NEMA DICOM 3.0 standard as documented in the MIStar DICOM 3.0 Conformance Statement.

Software Development and Testing

The MIStar software package was designed, developed, verified and validated according to the procedures described in the Software Information section: Software Development Process.

Comparison with Predicate

MIStar is a stand-alone software package that operates on an Intel-based PC platform that satisfies the minimum system requirements. MIStar provide digital image processing and measurement capability. It can also communicate DICOM images with remote viewing stations or server systems over a medical imaging network.

MIStar also provides image post-processing as such does not have contact with the patient, nor does it control any devices that acquire medical images or sustain life. The algorithms used to calculate parametric parameters are similar to CT perfusion2 and Functool. It further requires the intervention of a physician in setting necessary parameters and in assessing resultant images.

The functional features of this package are substantially equivalent to that of eFilm Workstation with Modules (K020995), CT Perfusion 2 (K010042) and Advantage Windows with Functool option (K960265). The use of MIStar does not result in any additional potential hazards when compared to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2004

Apollo Medical Imaging
Technology Pty Ltd.
% Ms. Laura Danielson
Responsible Third Party Official
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K043350
Trade/Device Name: MIStar
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 12, 2004
Received: December 6, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K043350

Device Name: MIStar

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Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043350

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